510(k) Summary

ILLICO® FS Facet Fixation System
Date Prepared: July 20th, 2012

NOV 2 8 2012

I	**Company:**	Alphatec Spine, Inc. 5818 El Camino Real Carlsbad, CA 92008. USA
II.	**Contact:**	Trevor J. Denbo Regulatory Affairs Specialist Telephone: 760-494-6951 Fax: 760-431-0289
III.	**Product Name:**	ILLICO® FS FACET FIXATION SYSTEM
IV.	**Common Name:**	Facet Screw Spinal Device
V.	**Regulation Number:**	None
VI.	**Classification Product Code:**	MRW
VII.	**Predicate Devices:**	Raptor™ Facet Fixation System - K110170 Chameleon Fixation System – K071420

VIII. Description:

The ILLICO FS System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The system is comprised of the Facet Screw and Facet Lag Screw offered in two diameters (4.5mm and 5.0mm) and instrumentation. The implant provides bilateral facet fixation, with or without bone graft, at single or multiple levels and can be used in conventional or percutaneous surgical procedures. The implants are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI).

IX. Indications for Use:

The ILLICO® FS Facet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. ILLICO® FS Facet Fixation System is intended for bilateral facet fixation, with or without bone graft, at single or multiple levels from L1-S1 inclusive. The facet fixation system is indicated for treatment of any or all of the following:

- degenerative disc disease (DDD) as defined by back pain of discogenic origins confirmed by history and radiographic studies
- degenerative disease of the facets with instability
- trauma (i.e. fracture or dislocation)
- spondylolisthesis

- spondylolysis
- pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity

X. Summary of the Technological Characteristics:

The technological characteristics, materials, and indications for use of the ILLICO® FS Facet Fixation System is substantially equivalent to the previously cleared predicates. The subject device differs from the predicates as follows:

- Addition of Facet Screws with diameters of 4.5mm and Facet Lag Screws with diameters of 4.5mm and 5.0mm and a range of lengths for each.
- A minor dimensional change of the screw head and screw driver

The facet screw is a dual lead self-tapping titanium screw with a positive (male) hexalobular drive feature. The spherical feature of the screw mates with the spherical surface of the washer allowing for angulations of the washer to accommodate differences in the anatomy between patients. The washer also distributes the compression force across a larger surface area, reducing the stress on the dorsal surface of inferior facet joint. The internal threads located in the hexalobular feature are used if axial force is needed during the removal of the screw. The ILLICO® FS Facet Fixation System thread profile is designed to the standard for cortical bone screws (ASTM F543-07). The thread is also a dual lead, which minimizes the number of rotations needed to implant the screw. The integral tapping flutes allow the screw to be placed without tapping prior to screw placement

XI. Discussion of the Non-clinical Testing:

Mechanical static and dynamic testing was performed which provides reasonable assurance of safety and effectiveness for its intended use. Performance testing was performed comparing the subject and predicate devices per the recognized consensus standards and per the guidance document, *Guidance for Industry and FDA Staff: Spinal System 510(k)s* (2004). The following testing was performed per ASTM F 543-07 and ASTM F 2193-02:

- Torsion Yield Strength
- Pull Out Force
- Static Bending and Dynamic Testing

The above tests produced acceptable results and demonstrate that the ILLICO® FS Facet Fixation System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 28, 2012

Alphatec Spine, Incorporated
% Mr. Trevor J. Denbo
Regulatory Affairs Specialist
5818 El Camino Real
Carlsbad, California 92008

Re: K123218
Trade/Device Name: ILLICO FS Facet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: October 12, 2012
Received: October 31, 2012

Dear Mr. Denbo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123218

Device Name: **ILLICO FS Facet Fixation System**

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- **spondylolysis**
- **pseudoarthrosis and failed previous fusion which are symptomatic or which may cause secondary instability or deformity**

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123218